of 1 milliliter and proceed as directed in paragraph (e)(2) of that section.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted suspension.

[39 FR 33668, Sept. 19, 1974, as amended at 46 FR 25608, May 8, 1981]

§ 444.442g Neomycin sulfate-polymyxin B sulfate-hydrocortisone otic suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-hydrocortisone otic suspension contains in each milliliter 3.5 milligrams neomycin, 10,000 units polymyxin B, and 10 milligrams hydrocortisone in a suitable and harmless vehicle. It may also contain one or more suitable and harmless buffers, dispersants, and preservatives. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. It is sterile. Its pH is not less than 3.0 and not more than 7.0. The neomycin sulfate used conforms to the standards prescribed by § 444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by § 448.30(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*c*) The batch for potency, sterility, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch:

(*1*) For all tests except sterility: A minimum of six immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(ii) *Polymyxin B content.* Proceed as directed in § 436.105 of this chapter, except add to each concentration of the polymyxin B standard response line a quantity of neomycin to yield the same concentration of neomycin as that present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Dilute an accurately measured representative portion with sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except if the steroid prevents in lieu of 1 milliliter and proceed as disolubilization, use 0.25 milliliter of sample as directed in paragraph (e)(2) of that section.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

[40 FR 22252, May 22, 1975, as amended at 50 FR 19919, May 13, 1985; 55 FR 18598, May 3, 1990]

§ 444.442h Neomycin sulfate-polymyxin B sulfate-hydrocortisone otic solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate-polymyxin B sulfate-hydrocortisone otic solution contains in each milliliter 3.5 milligrams of neomycin, 10,000 units of